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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,619	11/20/2003	John P. Daley	IVGN 140.1 CON	6354
65482 7590 06/27/2007 INVITROGEN CORPORATION C/O INTELLEVATE P.O. BOX 52050 MINNEAPOLIS, MN 55402			EXAMINER KIM, TAEYOON	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 06/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/716,619

Applicant(s)

DALEY ET AL.

Examiner

Taeyoon Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55 and 76-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55 and 76-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/13/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 55 and 76-98 are pending.

Response to Amendment

Applicant's amendment and response filed on Apr. 13, 2007 has been received and entered into the case.

Claim 61 is canceled, claim 98 is newly added, and claims 55 and 76-98 are pending and have been considered on the merits. All arguments have been fully considered.

The claim objection to claim 61 and the claim rejection under 35 U.S.C. §112, first paragraph to claims 77 and 88 are withdrawn due to the amendment.

Applicant's arguments with respect to the statutory double patenting to claims 55 and 79 have been fully considered and are persuasive. The rejection of claims 55 and 79 has been withdrawn.

Terminal Disclaimer

The terminal disclaimer filed on Apr. 13, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,733,746 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Priority

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent

application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/792299 (now US 6,766,746), fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Claim 76 and its dependent disclose a method of expanding recombinant CD34+ hematopoietic cells with a serum-free medium and culturing the cells in suspension in the absence of stromal cells. First of all, this limitation is not supported by the specification of the current application because the scope of the claim is broader than the limitation given in the specification. The disclosure of the specification is that the method of the current invention utilized a specific serum-free medium instead of ANY serum-free medium. The serum-free medium of the current invention has specific ingredient comprising N-acetyl-L-cysteine, however, claim 76 and its dependents disclose ANY serum-free medium. The prior-filed application of '299 also did not support such broad limitation of the serum-free medium. Therefore, the benefit of prior-filed application is not granted for the claims 76 and its dependents. The earliest filing date of the current application is considered Nov. 20, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 55 and 76-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (WO 95/06112) in view of Darfler (US 4,927,762) in light of Walsh et al. (1994) and Hamilton et al. (WO 93/20195).

Claims 55 and 76-98 are drawn to a serum-free eukaryotic cell culture medium comprising various ingredients and a method of expanding recombinant CD34+ hematopoietic cells using a serum-free medium in suspension culture in the absence of stromal cells, and limitations to the serum-free medium comprising N-acetyl-L-cysteine, and other supplements including amino acids, cytokines, growth factors, glucocorticoid (hydrocortisone); limitations to the cells being expanded at 37°C for 6-8 days.

Smith et al. teach a method of expanding human CD34+ hematopoietic cells in suspension culture using a serum-free medium (see Abstract) comprising amino acids (see p.7, lines 5-12), cytokines (see Table 7), growth factors (see p.7, lines 14-24), and hydrocortisone (see p.9, lines 19-24). Smith et al. also teach the culture/expansion

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being at 37°C (see p.20 line 23) and for 5 to 7 days (see p.20, line 25). Smith et al. further teach administration of hematopoietic cells expanded to a patient (see p.14, lines 26-33).

Smith et al. do not teach the use of N-acetyl-L-cysteine in the culture medium.

Darfler teaches the use of antioxidant such as N-acetyl-L-cysteine (N-acetylcysteine) in the culture of lymphoid (see Abstract and Example 3).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use N-acetyl-L-cysteine of Darfler in the method of Smith et al.

The skilled artisan would have been motivated to make such a modification because the antioxidant such as N-acetyl-L-cysteine improves lymphoid survival and growth when culture in serum-free medium, as a protective agent and very effective at removing the toxicity due to oxidizing agents present in basal tissue culture media (see column 5, lines 58-67).

The person of ordinary skill in the art would have had a reasonable expectation of success in adding N-acetyl-L-cysteine in the medium of Smith et al. to improve the survival and growth of hematopoietic cells.

Although Smith et al. in view of Darfler do not particularly teach all the ingredients listed in claim 55, it would have been obvious for a person of ordinary skill in the art to modify the serum-free medium of Smith et al. in view of Darfler to optimize the outcome of hematopoietic cell culture by addition various well known components used in cell culture. Since the ingredients listed in claim 55 are individually well known in the art to

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be used as common components of cell culture media, a person of ordinary skill in the art would have had motivation to modify by adding or removing one or more ingredients in the serum-free medium of Smith et al. in view of Darfler. Unless there is clear evidence that the medium of Smith et al. in view of Darfler is different from the medium of the current invention, the examiner takes the position that the medium of Smith et al. in view of Darfler is the same as the claimed invention.

Although Smith et al. in view of Darfler do not particularly teach the use of recombinant CD34+ hematopoietic cells, it would have been obvious for a person of ordinary skill in the art use any kind of hematopoietic cells expressing CD34 surface marker because the fact that whether the cells are recombinant or not would not provide any patentable weight on the claimed method of expanding hematopoietic cells. Furthermore, the recombination technique is well known in the art even for hematopoietic cells as supported by Walsh et al. or Hamilton et al. teaching virally transduced hematopoietic progenitor cells, and since the method of Smith et al. is capable of expanding hematopoietic cells, it is clear that the method of Smith et al. would be able to carry out the intended use of expanding the recombinant CD34+ hematopoietic cells of the current invention.

M.P.E.P. § 2111.02 reads, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." As such, the limitation "the

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recombinant CD34+ hematopoietic cells" does not affect the patentability of the claimed composition/method. Compositions are defined by their physical, structural, and chemical properties, not by an intended use or application. Methods are defined by their constituent steps, not by an intended use or application.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

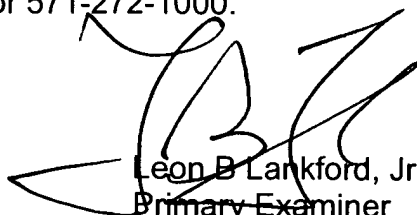
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim
Patent Examiner
Art Unit 1651



Leon B. Lankford, Jr.
Primary Examiner
Art Unit 1651